U.S. CONSUMER PRODUCT SAFETY COMMISSION
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Mr. Peter G. Mayberry
Executive Director
Healthcare Compliance Packaging Council
131 E. Broad St., Suite 206
Falls Church, VA 22046

Dear Mr. Mayberry:

This letter concerns your letter of March 17, 2003, in which the Healthcare Compliance Packaging Council (HCPC) requested two changes to the Commission's regulatory requirements concerning child-resistant packaging under the Poison Prevention Packaging Act (PPPA).[1] The changes requested by the HCPC related to the regulatory requirements for testing the ability of unit dose, *i.e.,* non-reclosable, child-resistant (CR) packaging to resist attempts by children to open it. The HCPC's specific requests were:

1. "The definition of test failure for unit dose packaging should be an objective standard, *i.e.,* 'any child who opens or gains access to more than 8 individual units during the full 10 minutes of testing.'"[2]

2. "Allow type testing for unit dose packaging under the protocol."[3]

On May 12, 2003, the Commission's Office of the General Counsel docketed the first HCPC request as Petition PP 03-1. The current CPSC regulatory definition of a child-resistance test failure for unit packaging is "any child who *opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness*, or a child who opens or gains access to more than 8 individual units, *whichever number is lower . . .*" 16 C.F.R. § 1700.20(a)(2)(ii)(*emphasis added).* Thus, Petition PP 03-1 amounts to

[1] 15 U.S.C. §§ 1471-1476.
[2] March 17, 2003 HCPC letter at 7.
[3] March 17, 2003 HCPC letter at 9.

a request to delete consideration of the toxicity of the substance as a unit packaging test failure criterion.

Because CPSC regulations do not preclude "type testing" as defined by the HCPC, the second requested change was not docketed as a petition for rulemaking. The HCPC was informed of this by letter of May 27, 2003 from Assistant General Counsel Stephen Lemberg.

As discussed below, under applicable regulations the Commission has voted 2-0 to deny Petition PP 03-1.[4]

In reaching its decision, the Commission considered your letter of March 17, 2003 and the materials submitted with it, your additional submissions of May 5, 2003 and December 13, 2004; the twenty-eight public comments received on the petition; the extensive materials prepared by the Commission staff and presented in the staff briefing package, *Briefing Package: Petition to Amend Child-Resistance Testing Pass/Fail Criterion for Unit Packaging (PP 03-1),* (the Staff Briefing Package); the memorandum of December 21, 2004 from Suzanne Barone, Ph.D., Project Manager for Poison Prevention, Directorate for Health Sciences, to the Commission, *Healthcare Compliance Packaging Council (HCPC) Response to CPSC Staff's Recommendation to the Commission Regarding the Petition to Amend Child Resistance Testing Pass/Fail Criterion for Unit Packaging (PP 03-1)*; and other information.

I. Consideration of Toxicity under the PPPA

The PPPA allows the Commission to require, by rulemaking, "special," *i.e.*, "child-resistant," packaging for a "household substance" if:

> (1) the degree or nature of the hazard to children in the availability of *such substance*, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting *such substance*, and
> (2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for *such substance*.[5]

For purposes of the PPPA, a "household substance" is a substance customarily available to individuals for storage, consumption or use in the household and which is a hazardous substance under the Federal Hazardous Substances Act; a food, drug or cosmetic under the

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[4] 16 C.F.R. pt. 1051.

[5] 15 U.S.C. §1472(a) (*emphasis added*). "[S]pecial packaging means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a *toxic or harmful amount of the substance contained therein* within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time." 15 U.S.C. § 1471(4) (*emphasis added*).

Federal Food, Drug, and Cosmetic Act; or a fuel stored in a portable container and intended for use in the heating, cooking, or refrigeration systems of a house.[6]

The Commission is not permitted to prescribe specific package designs, product content, or package quantity.[7] In essence, the Commission is authorized to regulate substances, *not* packaging, and to do so on a performance basis.

The Commission's testing protocol regulations at 16 C.F.R. part 1700 are intended to assure that the packaging at issue performs so as to make it significantly difficult for a child to access a toxic or harmful amount of the particular substance in question. The Commission's rules requiring CR packaging that meets these protocols are then established on a substance-specific, and where appropriate, quantity-specific basis, for example, requiring CR packaging specifically for ibuprofen, loperamide, acetaminophen, iron-containing drugs and dietary supplements, etc.[8]

Under the PPPA, "child-resistant" packaging is not "child-proof" packaging. Thus, the regulatory testing protocol defines "child-resistant" packaging for both unit and non-unit packaging as that which is expected to prevent 80% to 85% of children tested from accessing a toxic or harmful amount of the substance in question.

In the case of non-unit, *i.e.,* reclosable, packaging, a test failure for a package is defined as a single access, which assumes any access could constitute access to an amount that would cause serious illness or serious injury.[9] For unit, *i.e.,* non-reclosable, packaging, a test failure is access to the *lesser* of the number of units that contain a toxic amount of the product in question or more than eight individual units.

The numerical criterion was established to provide the unit packaging industry with a benchmark against which to develop packaging. That benchmark was originally set at access to more than five units. The benchmark was later raised to be access to more than eight units. However, the preamble statement accompanying that change emphasized that, as required by the PPPA, the toxicity of the substance to be packaged would still govern if access to eight or fewer units could produce serious personal injury or serious illness:

> A change from more than 5 to more than 8 individual units will not compromise safety or reduce the child protection quality of special packaging because the number of individual units constituting the amount that may produce serious personal injury or serious illness will prevail in establishing the test failure when such number is 8 or less.[10]

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[6] 15 U.S.C. § 1471(2).
[7] 15 U.S.C. § 1472(d).
[8] *See* 16 C.F.R. § 1700.14.
[9] 16 C.F.R. § 1700.20(a)(2)(ii).
[10] 38 Fed. Reg. 1,510 (January 15, 1973).

Thus, under the current CPSC child-resistance testing protocol, a manufacturer that believes its product is not toxic until access is gained to some number of units exceeding eight need not rely on testing beyond the "more than eight" criterion. However, the "lesser number" requirement remains in place in the current regulations to satisfy the statutory protectiveness criterion of the PPPA.

II. Whether Unit Packaging is "Inherently Safer" then Reclosable Packaging

In support of the request to delete consideration of toxicity, the HCPC asserts that unit packaging is "inherently safer" than reclosable packaging.[11] This assertion is not relevant to the statutory criteria for imposition of a CR packaging requirement, which require CR packaging where necessary to "protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance . . ." and that CR packaging "does not mean packaging which all such children cannot open . . . in a reasonable time." 15 U.S.C. § 1471(4).

Conclusion

Based on the foregoing analysis and the information before it, the Commission has denied the petition. In summary, the basis for denial is that the action requested would decrease the protectiveness of the Commission's current regulations.[12]

Sincerely,

Todd A. Stevenson

[11] The CPSC staff analysis on this issue concludes that the data and analysis presented by the HCPC do not support the conclusion that unit packaging is "inherently safer." *See Staff Briefing Package* at 6-7.

[12] Example of such situations provided by commenters on Petition PP 03-1 include clonidine, morphine, the sustained release opiates, such as oxycodone, digoxin, oral hypoglycemic, and tricyclic antidepressants. *See, staff Briefing Package* at p. 10